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Original Article

Efficacy of a Hospital Discharge Transition Plan in the care competence of patients with chronic conditions and their family caregivers: a clinical trial*

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Highlights: (1) The CUIDAR validated tool was used, which measures care competence. **(2)** It is necessary to strengthen transitional care at hospital discharge. **(3)** The patients' adherence to the treatment was moderate. **(4)** The educational intervention that was created increased the caregivers' care competence.

Objective: to assess the efficacy of a Hospital Discharge Transition Plan in the care competence and in adherence to the therapy of dyads comprised by patients with non-communicable chronic diseases and their caregivers. **Method:** a controlled and randomized clinical trial; the sample was comprised by 80 dyads of patients with chronic conditions and their caregivers, randomly allocated as follows: 40 to the control group and another 40 to the intervention group. The instruments to characterize the patient-caregiver dyad, the patients' and caregivers' care competence and the patients' adherence to the treatment scale were applied. The "*CUIDEMOS* educational intervention" was applied to the intervention group; in turn, the control group was provided usual care with the aid of a booklet, with phone follow-up via at month 1. **Results:** 52.5% of the patients and 81.3% of the caregivers were women. The patients' and caregivers' mean ages were 69.5±12.6 and 47.5±13.1 years old, respectively. The Hospital Discharge Transition Plan increased the scores in the "knowledge", "uniqueness", "instrumental", "enjoying", "anticipation" and "social relations" dimensions, as well as the global care competence of the patients and family caregivers; in addition to the following factors: medications, diet, stimulants control, weight control, stress management, and global adherence to the therapy by the patient. There were no statistically significant differences between the control and intervention groups. **Conclusion:** the Hospital Discharge Transition Plan increased the patients' and family caregivers' care competence after the intervention, as well as the patients' adherence to the treatment. However, there were no differences between the control and intervention groups, possibly due to the similarity of the activities.

Clinical Trial Registry: NCT04175860 (11/2019).

Descriptors: Caregiver Burden; Transitional Care; Chronic Disease; Caregivers; Patient Education as Topic; Treatment Adherence and Compliance.

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Introduction

Transitional care is the orderly and uninterrupted path of a patient among health professionals and environments during the course of chronic or acute diseases. However, this transition is frequently affected by discontinuity and lack of coordination related to deficient communication about care, unclear roles and responsibilities, diluted personal ownership over care and tension regarding the role due to system limitations(1-2). Previous research studies have focused on assessing the effect of transitional care interventions on readmission rates and the costs for health institutions, leaving aside other results that can also be important(3), such as the patients' adherence to the therapy and the care competence in patient-caregiver dyads at home(4-5).

Care competence is defined as "the ability, skill and preparedness of a person with a chronic condition and their family caregiver to perform the care tasks at their home"(6). The patients and their families should commit to adopting the necessary competencies to handle their chronic condition, adhering to the treatment and incorporating healthier habits that allow them to recover their health and quality of life(7). Adherence to the treatment is defined as the "the set of actions that reflect participation in a treatment program and seek to avoid risk behaviors, incorporating the medical recommendations into everyday routines and leading a healthy lifestyle"(8-9). Adherence to the treatment exerts an impact on the patients' quality of life, as well as on the prevention of long-term complications, hospitalizations and readmissions(8,10).

Therefore, hospital discharge represents a critical and crucial moment for family caregivers and patients alike; it implies making decisions about care, changing the medications prescribed and adapting to them, adopting new routines or seeking professional help when required(11). It is precisely at this moment that, in addition to adherence to the treatment, the evaluation, assessment and analysis of the home care competence in patients with chronic conditions and their family members gain importance within the transitional care plan during hospital discharge. This is because patients with cardiovascular chronic conditions are usually provided with complex guidelines for their care and therapeutic management(6). Therefore, as long as the importance of proper welcoming and understanding about the discharge plan by the patient-caregiver dyad is duly sized, there might be an impact on the reduction in readmissions due to preventable causes, on the costs for health services, on people's stress and on care continuity(6).

Consequently, the general objective of the study was to assess the efficacy of a Hospital Discharge Transition Plan in the care competence of dyads comprised of patients with cardiovascular chronic conditions and their family caregivers and in the patients' adherence to the treatment. The hypothesis is that the patients with cardiovascular chronic conditions and family caregivers that underwent the Hospital Discharge Transition Plan intervention would report higher care competence levels than those who were offered the usual institutional discharge plan. Likewise, the patients that underwent the intervention would present higher therapeutic adherence levels than those from the comparison group.

Method

Type of study

A controlled and randomized clinical trial was conducted, which was registered in the Clinical Trial Registry under code NCT04175860 (11/2019).

Population

The clinical trial participants were patients diagnosed with some cardiovascular chronic condition who were hospitalized with their family caregivers.

Eligibility criteria

The participants were adult people hospitalized in any of the three health institutions that will be specified below, who had been diagnosed with at least one cardiovascular chronic condition (hypertension and/or diabetes *mellitus*) a minimum of 6 months ago and who were cared for by a family caregiver, also an adult. The individuals excluded were those that also presented some psychiatric diagnosis and who were not able to properly communicate with the researchers due to some health problem.

Locus

The patient-caregiver dyads were recruited in the hospitalization and urgency services of three low- and medium-complexity health care institutions, located in the metropolitan area of Bucaramanga, Santander, Colombia, namely: *Empresa Social del Estado Hospital San Juan de Dios* from the municipality of Floridablanca, a public and secondary-level or low-complexity hospital; *Clínica Bucaramanga*, a private and tertiary-level or medium- and high-complexity health care institution; and *Empresa Social del Estado Clínica Guane* from Floridablanca, a public and primary-level or low-complexity health care institution.

Definition of the sample

Sample size was calculated considering a 95% confidence interval, 80% statistical power, 1:1 ratio and Delta of 9 with a standard deviation of 13.54 points in the care competence between the intervention and control groups, according to a pilot test conducted with 50 dyads other than those included in this study. 15% was added for possible follow-up losses, therefore reaching a total of 80 patient-caregiver dyads: 40 in the intervention group and another 40 in the control group.

Of all 557 patients admitted during the recruitment period in the three health institutions from the metropolitan area of Bucaramanga, 157 had cardiovascular chronic conditions, 114 were cared for by family caregivers, 114 met the selection criteria, 95 dyads accepted to take part in the study and 15 were excluded for other reasons. Finally, the sample was comprised by 80 patient-caregiver dyads from three health institutions (Institution A: 33 dyads; Institution B: 45 dyads; and institution C: 3 dyads), which were randomly allocated as follows: 40 to the intervention group and another 40 to the control group.

Control group

The activities were conducted with 40 dyads, which were offered general care and indications at their hospital admission as established by each institution; in turn, they were provided information about prevention of falls, accidents at home and adherence to the treatment. These indications were given by the research team members with the aid of an educational booklet. At month 1, a phone follow-up process was conducted to apply the care competence instrument.

Intervention group

A total of 40 dyads were approached, which were offered four theoretical didactic interventions with the aid of the Transition Plan Educational Booklet called "*CUIDEMOS* Educational Intervention"(12) about home-based care for patients with chronic conditions and their family caregivers, addressing topics such as the following: information about hospital discharge; care measures to follow a healthy diet; routine and recommendations for physical exercise; care measures regarding the cardiovascular and modifiable risk factors; precautions to improve adherence to the treatment; and knowledge regarding the patients' and caregivers' roles to reduce the risk of complications and to allow better quality of life. This booklet has been face-validated by experts, patients and caregivers (results not published).

When the patient-caregiver dyads were recruited in the hospitalization services, they were offered the first intervention about adherence to the treatment: administration at the proper time and dose; aids to remember taking the medications; and importance of adhering to the treatment. Each dyad was handed in the printed booklet.

Subsequently, they underwent three weekly educational interventions via telephone calls, using the Transition Plan Educational booklet called "*CUIDEMOS* Educational Intervention" as support, which emphasizes the following topics and contents:

- Healthy diet that includes water consumption, reduction in the intake of ultra-processed food products and increased fruit and vegetable consumption.
- Physical activity at least three times a week, lasting 30 minutes and according to each patient's health status.
- Recommendations on warning signs and risk factors for the chronic diseases presented by the study participants.

Likewise, the care competence instrument was applied at month 1 after the intervention.

Variables

The main outcome was care competence in patients with chronic conditions and their family caregivers; another primary outcome was the patients' adherence to the treatment.

The variables involved in the study were the following: sociodemographic variables (gender, age, origin, marital status, religion, occupation, socioeconomic level); time since the patient was diagnosed with the cardiovascular chronic condition; estimated burden for the family; time since the caregiver started caring for their family member; caregiver burden perception in order to determine whether they had care burden or not; and patient's adherence to their treatment.

Instruments used to collect the information

The following instruments were applied for data collection:

The first one, created by the nursing care for chronic patients group at the National University of Colombia (*Grupo de Cuidado de Enfermería al Paciente Crónico-Universidad Nacional de Colombia*, GCPC-UN), was the survey for the characterization of the patient with a chronic condition (GCPC-UN-P©) and their caregiver (GCPC-UN-C©) dyad(13), which addresses aspects inherent to the patients' and caregivers' sociodemographic profiles, to the chronic diseases, to their care and to the burden perception level(13). The socioeconomic level variable is measured as the proxy for the socioeconomic level reported by the participants in the aforementioned instrument; it is a classification of the houses or land lots and an approximation to the hierarchized socioeconomic difference, which is classified as follows by the Colombian National Statistics Department: 1) Low-Low, 2) Low, 3) Average-Low, 4) Average, 5) Average-High, and 6) High.

The extended version of the CUIDAR instrument, both for patients and for caregivers, was also developed by GCPC-UN with the purpose of determining the care competence of patient-caregiver dyads. This tool has six dimensions derived from the CUIDAR acronym (CARE in Spanish): *conocimiento* (knowledge) (9 items); *unicidad: condiciones personales* (uniqueness: personal conditions) (13 items); *instrumental y procedimental* (instrumental and procedural) (8 items), *disfrutar: bienestar* (enjoying: well-being) (12 items); *anticipación: predicción* (anticipation: prediction (6 items); and *relación social e interacción* (social relations and interaction) (12 items). There are a total of 60 items that are measured according to a Likert scale with scores from 0 to 3, where 0 is never or almost never, 1 means a few times, 2 is frequently, and 3 represents almost always or always. The questionnaire total score is obtained by adding up the values for each item. The higher the total score, the better the care will be(14).

Finally, a questionnaire on adherence to the treatment in patients with arterial hypertension was used, which was translated and validated for Colombia(9). That scale has six dimensions: medications, diet, stimulants control, physical exercise, weight control and stress management; it includes a total of 28 items that are measured with a Likert-type scale from 1 to 4 points, where 1 corresponds to never, 2 is sometimes, 3 means most of the time, and 4 represents all the time. The total score is obtained by adding up the items; the higher the score, the better the adherence to the treatment and the range is from 29 to 112 points. The cutoff point is 84: higher scores are classified as good adherence and lower ones, as non-adherence(9). Although not all the participants have hypertension, this instrument was used because it evaluates the main and general indications for the adherence of patients with cardiovascular conditions.

Randomization

Randomization was performed in blocks without replacement by means of the software offered in www.randomization.com. The randomization frequency was applied by a person external to the research. Once each participant had met the selection criteria and agreed to participate in the study, the research assistant contacted the list administrator and reported the participant's name, age and gender to him, who then indicated the group to which the person should be allocated.

Data collection and masking

The participants' recruitment, intervention and follow-up were carried out from January to September 2022. Data collection was in charge of five research assistants: three students attending the last year of the nursing course and two nursing professionals.

Recruitment of the patient-caregiver dyads and the baseline measurement were performed in the internal medicine and urgency hospitalization services. The inclusion criteria were verified, the informed consent process was conducted with each patient-caregiver dyad, the assessment instruments were applied and each dyad was randomly allocated either to the intervention group or to the control group. The research team had no previous relationship with the participants. The baseline and final measurements were taken independently by masked personnel different from the people who conducted the control or intervention group activities and who were unaware of this condition.

Data analysis

The EpiData Software tool was used for double-typing and validating the information from the instruments applied. The Stata 14.0 software was used for the analysis. In the univariate analysis, proportions were calculated for the qualitative variables, normality of the quantitative variables was assessed through the Shapiro-Wilk test, mean values and standard deviations were calculated for the variables following a normal distribution and, in turn, median and interquartile range were obtained for the variables with a non-normal distribution. For the bivariate analysis, mean and standard deviation differences were calculated between the final and initial scores obtained in the instruments applied to each group, in addition to p-values by means of Students' paired t test. Subsequently, the means of the differences between the Delta values in the intervention and control groups were calculated, with a 95% confidence interval and p-value obtained with the Analysis of Variance test (ANOVA). Later on, these differences were adjusted by the initial score of the variable by means of an Analysis of Covariance (ANCOVA). An intention-to-treat analysis was performed; for such purpose, the baseline values were maintained in the variables with missing data during follow-up of the deceased and lost subjects, both in the control group and in the intervention group.

In addition, data analysis was performed in a masked way assigning a number to the "group" variable.

Validity and reliability

Referring to the psychometric values of the instruments, the extended version of CUIDAR, both for the patients and for the caregivers, has apparent validity, construct validity and reliability, with a Cronbach's alpha of 0.96 in Colombia(14). In the current study, Cronbach's alpha was 0.95 for the patients and 0.93 for the caregivers.

The questionnaire on adherence to the treatment in patients with arterial hypertension has construct validity and reliability, with a Cronbach's alpha of 0.74 for Colombia(9). In this study, Cronbach's alpha was 0.89. Zarit's caregiver burden scale has inter-observer reproducibility with an intraclass correlation coefficient of 0.81 and Cronbach's alpha of 0.84(15). In this study, Cronbach's alpha was 0.87. All the values in the current study were calculated before the intervention.

Ethical aspects

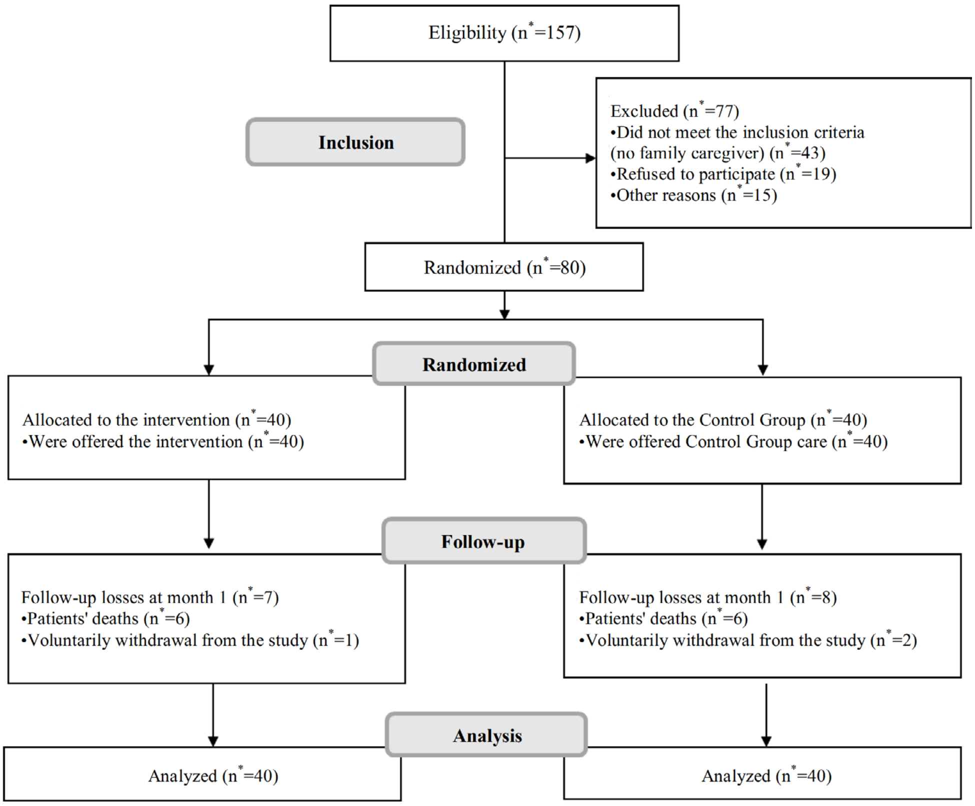
The study was conducted in compliance with Colombian resolution No. 8,430 from 1993, which establishes the scientific, technical and administrative standards for research in health, and was approved by the Bioethics Committee of the University of Santander. Informed consent was obtained from all the participants, both patients and caregivers. The information was handled in a confidential manner and the study participants' privacy was respected. The participants were identified by means of codes both in the instruments and in the database for the anonymization process; only the researchers can access the information and the records will be kept for five years. No harm or damages were presented in this research.

Results

The study report followed the Consolidated Standards of Reporting Trials, (CONSORT) for reporting clinical trials.

Figure 1 shows the flowchart corresponding to the randomized clinical trial. A total of 80 patient-family caregiver dyads were included: 40 were randomly allocated to the control group and another 40 to the intervention group.

A total of 15 dyads were lost during the study: 12 due to the patients' dying, 6 from the control group and another 6 from the intervention group; in addition to 3 dyads that voluntarily decided to withdraw from the study, one of them from the intervention group and two from the control group. Therefore, it was only possible to follow-up a total of 65 dyads at month 1.



*n = Number of dyads

Figure 1 - Flowchart showing the results corresponding to selection of the patient-caregiver dyads

Table 1 shows the sociodemographic characteristics of the patients and family caregivers, both from the intervention group and from the control group. Although there were differences between the answer categories in some variables, the p-values were equal to or greater than 0.05 for the gender, age, origin, maximum schooling level, marital status, occupation, socioeconomic level and religion sociodemographic variables; in other words, the control and intervention groups were homogeneous.

Table 1 - Sociodemographic characterization of the patient-caregiver dyads from the control and intervention groups. Bucaramanga, Colombia, 2022

Variable	Patients		p[†]	Caregivers		p[†]
	Control	Intervention		Control	Intervention	
	n* (%)	n* (%)		n* (%)	n* (%)	
Gender			1.00			0.39
Male	19 (47.50%)	19 (47.50%)		6 (15.00%)	9 (22.50%)	
Female	21 (52.50%)	21 (52.50%)		34 (85.00%)	31 (77.50%)	
Age, mean	71 (10)	68 (14)	0.18[‡]	46 (11)	49 (15)	0.48[‡]
Origin			0.17			0.28
Santander	27 (67.50%)	31 (77.50%)		28 (70.00%)	31 (77.50%)	
Others	13 (32.50%)	9 (22.50%)		12 (30.00%)	9 (22.50%)	
Schooling			0.10			0.47
None	12 (30.00%)	5 (12.50%)		1 (2.50%)	0 (0.00%)	
Elementary School	6 (15.00%)	12 (30.00%)		12 (30.00%)	8 (20.00%)	
Incomplete Elementary School	6 (15.00%)	7 (17.50%)		1 (2.50%)	1 (2.50%)	
High School	4 (10.00%)	7 (17.50%)		11 (27.50%)	21 (52.50%)	
Incomplete High School	5 (12.50%)	2 (5.00%)		4 (10.00%)	2 (5.00%)	
Technical Level	0 (0.00%)	3 (7.50%)		6 (15.00%)	3 (7.50%)	
University Studies	5 (12.50%)	4 (10.00%)		4 (10.00%)	4 (10.00%)	
Graduate Studies	2 (5.00%)	0 (0.00%)		1 (2.50%)	1 (2.50%)	
Place of residence			0.07			0.04
Rural	9 (22.50%)	1 (2.50%)		8 (20.00%)	2 (5.00%)	
Urban	31 (77.50%)	39 (97.50%)		32 (80.00%)	38 (95.00%)	
Marital status			0.11			1.00
With a partner	21 (52.50%)	14 (35.00%)		14 (35.00%)	14 (35.00%)	
No partner	19 (47.50%)	26 (65.00%)		26 (65.00%)	26 (65.00%)	
Occupation			0.72			0.58
House chores	26 (65.00%)	26 (65.00%)		18 (46.15%)	16 (40.00%)	
Employee	2 (5.00%)	1 (2.50%)		5 (12.82%)	2 (5.00%)	
Autonomous worker	7 (17.50%)	5 (12.50%)		11 (28.21%)	13 (32.50%)	
Other	5 (12.50%)	8 (20.00%)		5 (12.82%)	9 (22.50%)	
Socioeconomic level			0.05			0.16
Low	22 (55.00%)	10 (25.00%)		18 (45.00%)	9 (22.50%)	
Average-Low	10 (25.00%)	15 (37.50%)		12 (30.00%)	15 (37.50%)	
Average	5 (12.50%)	10 (25.00%)		7 (17.50%)	11 (27.50%)	
Average-High	2 (5.00%)	5 (12.50%)		2 (5.00%)	5 (12.50%)	
Others	1 (2.50%)	0 (0.00%)		1 (2.50%)	0 (0.00%)	
Religion			0.26			0.10
Catholics	33 (82.50%)	37 (92.50%)		32 (80.00%)	35 (87.50%)	
Christians	4 (10.00%)	1 (2.50%)		6 (15.00%)	0 (0.00%)	
Atheists	3 (7.50%)	1 (2.50%)		0 (0.00%)	1 (2.50%)	
Others	0 (0.00%)	1 (2.50%)		2 (5.00%)	4 (10.00%)	

*n = Number of people; [†]p = p-value obtained in the Chi-square test; [‡]p = p-value obtained in the Student’s t test

Table 2 describes the characteristics of the diseases and of family care; it is evidenced that most of the participants have hypertension and diabetes *mellitus*. Regarding the caregivers' burden, the proportion of caregivers with intense burden in the intervention group is higher (20%) than in the control group (2.5%), with p-value=0.04.

Table 2 - Health and care aspects of the patient-caregiver dyads from the control and intervention groups. Bucaramanga, Colombia, 2022

Variable	**Control**	**Intervention**	**p**†
	n*=40	**n*=40**	
Hypertension			0.07
No	6 (15.00%)	13 (32.50%)	
Yes	34 (85.00%)	27 (67.50%)	
Type II Diabetes *Mellitus*			0.37
No	25 (62.50%)	21 (52.50%)	
Yes	15 (37.50%)	19 (47.50%)	
Hypertension and diabetes			0.79
No	30 (75.00%)	31 (77.50%)	
Yes	10 (25.00%)	9 (22.50%)	
Time since diagnosis of the chronic disease, mean (SD)§	115 (102)	149 (134)	0.20‡
Number of medications, mean (SD)§	4 (2)	4 (2)	0.75‡
Time as caregiver in months, mean (SD)§	49 (46)	58 (72)	0.52‡
Daily hours devoted to caring for the family member, mean (SD)§	9 (7)	10 (8)	0.64‡
The caregiver is:			0.07
Spouse	8 (20.00%)	16 (40.00%)	
Father/Mother	0 (0.00%)	1 (2.50%)	
Son/Daughter	23 (57.50%)	21 (52.50%)	
Other	9 (22.50%)	2 (5.00%)	
Care burden			0.04
None	31 (77.50%)	23 (57.50%)	
Mild	8 (20.00%)	9 (22.50%)	
Intense	1 (2.50%)	8 (20.00%)	

*n = Number of people; †p = p-value obtained in the Chi-square test; ‡p = p-value obtained in the Student's t test; §SD = Standard Deviation

Table 3 shows the care competence in the patient-caregiver dyads from the control and intervention groups before and after the intervention, and the Delta between these values; both in the control and intervention groups, a statistically significant increase was observed in the scores obtained by the patients and family caregivers in the uniqueness, instrumental, enjoying, anticipation and social relations dimensions; in addition, the total competence score increased in both groups, with p-values<0.05. The patients' and caregivers' knowledge was also increased in the intervention group, with p-values<0.001.

Similarly, regarding the patients' adherence to the treatment, Table 3 also shows the mean values and standard deviations corresponding to the pre- and post-intervention scores by factors and adherence totals between the groups, as well their Delta values. An increase was observed in the post-intervention scores in relation to the pre-intervention values in the medications, diet, stimulants control, weight control, stress management and total adherence factors, both in the control and in the intervention group, with p-values<0.05.

Finally, no statistically significant differences were observed in Table 4 between the Delta values corresponding to the control and intervention groups, either in the global care competence score or by dimensions, for the patients and caregivers and adherence to the treatment alike, both in the unadjusted and adjusted differences.

Table 3 - Effect of the Hospital Discharge Transition Plan intervention on the care competence in the patient-caregiver dyads and on the patients' adherence to the treatment, in the control and intervention groups. Bucaramanga, Colombia, 2022

Factor	Control group				Intervention group			
	Mean				Mean			
	(Standard Deviation)				(Standard Deviation)			
Patients	**Pre***	**Post†**	**Delta**	**p‡**	**Pre***	**Post†**	**Delta**	**p‡**
Knowledge	17.00 (5.80)	23.35 (8.12)	6.35 (7.65)	<0.001	18.45 (6.42)	23.92 (8.44)	5.47 (6.60)	<0.001
Uniqueness	24.17 (5.39)	29.95 (7.34)	5.78 (8.27)	<0.001	22.85 (5.18)	29.00 (9.06)	6.15 (9.38)	<0.001
Instrumental	14.23 (5.23)	16.52 (6.93)	2.30 (6.26)	0.03	15.25 (3.80)	18.20 (6.63)	2.95 (5.81)	0.003
Enjoying	22.02 (5.06)	26.75 (8.02)	4.72 (6.43)	<0.001	22.55 (4.53)	27.05 (7.50)	4.50 (6.81)	<0.001
Anticipation	9.45 (3.40)	13.75 (4.87)	4.30 (4.42)	<0.001	9.90 (4.00)	13.45 (5.69)	3.55 (5.02)	<0.001
Social relations	29.48 (5.83)	34.40 (3.28)	4.93 (6.61)	<0.001	29.05 (5.11)	33.20 (4.69)	4.15 (5.71)	<0.001
Total	116.35 (23.27)	144.73 (35.89)	28.38 (32.69)	<0.001	118.05 (22.86)	144.82 (38.71)	26.77 (32.61)	<0.001
Medications	3.41 (0.49)	3.61 (0.55)	0.20 (0.43)	0.006	3.55 (0.48)	3.78 (0.38)	0.23 (0.50)	0.005
Diet	2.89 (0.56)	3.37 (0.55)	0.47 (0.80)	<0.001	2.91 (0.49)	3.38 (0.58)	0.47 (0.64)	<0.001
Stimulants control	3.07 (0.80)	3.61 (0.48)	0.54 (0.86)	<0.001	3.23 (0.74)	3.46 (0.49)	0.23 (0.74)	0.06
Physical exercise	1.99 (1.01)	2.05 (1.01)	0.06 (1.13)	0.73	1.80 (0.81)	1.95 (0.75)	0.15 (0.87)	0.28
Weight control	2.75 (0.88)	3.35 (0.79)	0.60 (1.10)	<0.001	2.78 (0.69)	3.46 (0.76)	0.69 (0.99)	<0.001
Stress management	2.47 (0.84)	3.42 (0.91)	0.94 (0.95)	<0.001	2.50 (0.54)	3.52 (0.76)	1.02 (0.87)	<0.001
Adherence	78.82 (11.23)	90.10 (14.93)	11.27 (16.29)	<0.001	80.68 (11.47)	91.57 (11.77)	10.90 (14.79)	<0.001
Caregivers	**Pre***	**Post†**	**Delta**	**p‡**	**Pre***	**Post†**	**Delta**	**p‡**
Knowledge	19.83 (4.65)	27.70 (4.94)	7.88 (5.83)	0.3	21.35 (5.31)	29.00 (2.87)	7.65 (5.97)	<0.001
Uniqueness	26.48 (5.15)	34.42 (4.06)	7.95 (5.96)	<0.001	25.13 (5.28)	34.50 (3.48)	9.38 (6.53)	<0.001
Instrumental	17.38 (3.93)	22.67 (3.21)	5.30 (4.41)	<0.001	18.50 (3.93)	23.10 (2.78)	4.60 (4.02)	<0.001
Enjoying	26.58 (5.09)	33.15 (4.14)	6.57 (6.13)	<0.001	24.00 (4.56)	32.20 (5.99)	8.20 (6.47)	<0.001
Anticipation	12.00 (2.94)	16.67 (3.16)	4.68 (3.29)	<0.001	12.23 (3.44)	17.08 (2.82)	4.85 (3.61)	<0.001
Social relations	30.50 (5.14)	35.08 (2.62)	4.57 (5.32)	<0.001	30.25 (5.57)	35.03 (3.39)	4.78 (5.39)	<0.001
Total	132.75 (18.52)	169.70 (19.53)	36.95 (25.22)	<0.001	131.45 (19.97)	170.90 (18.72)	39.45 (25.52)	<0.001

*Pre = Before the intervention; †Post = After the intervention; ‡p = p-value obtained in the Student's paired t test

Table 4 - Unadjusted and adjusted differences of the Delta values corresponding to the care competence and adherence scores between the intervention group and control group. Bucaramanga, Colombia, 2022

Variable	Control Group			Intervention Group			Difference between Delta values				Adjusted difference			
	n*=40			n*=40										
	Delta	**95%CI†**		**Delta**	**95%CI†**		**Mean**	**95%CI†**		**p‡**	**Mean**	**95%CI†**		**p§**
Adherence	11.27	6.07	16.48	10.9	6.17	15.63	-0.38	-7.3	6.55	0.91	0.99	-4.9	6.89	0.74
Patients' care competence	28.38	17.92	38.83	26.78	16.34	37.2	-1.6	-16.1	12.93	0.83	-1.27	-15.7	13.23	0.86
Caregivers' care competence	36.95	28.88	45.02	39.45	31.29	47.61	2.5	-8.79	13.79	0.66	1.36	-7.15	9.87	0.75

*n = Number of patient-caregiver dyads; †95%CI = 95% Confidence Interval; ‡p = p-value obtained in ANOVA; §p= p-value obtained in ANCOVA

Discussion

This study evaluated the efficacy of a hospital discharge transition program when compared to usual care on therapeutic adherence and care competence in dyads comprised of patients with cardiovascular chronic conditions and their family caregivers. The most relevant results of the current study are the increase in the scores obtained in the dimensions and the global score for the care competence after the intervention, both in the patients and in the caregivers. However, this difference between the control and intervention groups was not statistically significant. Likewise, the scores corresponding to the patients' factors and adherence to the treatment increased after the intervention, although there were no differences when comparing the control group to the intervention group.

On the other hand, the results obtained in the sociodemographic characterization are similar to those found in other studies. Regarding gender, in a study conducted at the National Cancerology Institute in Bogotá, Colombia, the samples of patients (59.3%) and caregivers (73.8%) were mostly comprised of women, both in the control and in the intervention group(16). Another study, carried out in five Colombian regions, determined that most of the participants were women, both in the group of patients and in the group of caregivers(17). This is similar to what was found in another study that was carried out in two health institutions from Pasto, Colombia, where 71% of the family caregivers belonged to the female gender(18). This can be due to what is expected from the male and female roles, where women assume the care role, as they tend to be mostly committed to the well-being and quality of life of the person cared for(13).

In addition, it is noticed that the maximum schooling level attained by the participants is low, as they mostly have not completed any type of studies or may have finished elementary school. It is also observed that most of the participants earn low incomes, with prevalence of socioeconomic levels 1 and 2, that they devote to house chores and that they profess the Catholic religion. This is similar to what was found in other studies(11,18-20), implying that low schooling and economic income levels generate the need to offer educational and social support to people for them to manage their chronic diseases, adapted to their needs and knowledge; in other words, with a personalized approach in order to allow better management of their chronic conditions and greater adherence(16).

Referring to the care competence, after the educational intervention applied, an increase was observed in the knowledge, uniqueness, instrumental, enjoying, anticipation and social relations dimensions in this study, as well as in the global score; this was expected, as the intervention used in the study includes topics such as the importance of adhering to the treatment, education about healthy lifestyles such as diet and physical activity, and warning signs. No studies similar to this one were found, which hinders making comparisons with previous findings and their discussion. This fact evidences the relevance and novelty of this research because it evaluates a Hospital Discharge Transition Plan in the care competence and the patients' adherence to the treatment. Therefore, a comparison was made between this and other studies with similar target populations and interventions, finding similarities in the effect of the educational interventions on hospital discharge.

In this sense, a study conducted in Taiwan evaluated the efficacy of a Discharge Planning program for older adult victims of stroke and their family caregivers (158 dyads: 86 in the control group and 72 in the intervention group). The program included health education for hospitalized patients and referral services, phone follow-up after discharge and home visits. In addition, six research nurses were in charge of implementing the program, which was designed to meet the caregivers' discharge-related needs, improve balance between the caregivers' need for competencies, and improve their preparedness before discharge. The caregivers from the experimental group had significantly better nursing assessments and self-evaluations after the intervention than at the initial measurement. In addition, these results were significantly better in the intervention group than in the control group after implementing the program(21).

In Australia, the implementation of an evidence-based and systematic support program immediately after discharge and specifically designed for family caregivers of older adults hospitalized due to acute diseases was evaluated (141 dyads: 62 in the intervention group and 79 in the control group), so that the caregivers felt prepared to offer home-based care. The program was taught by a nurse, who conducted the training via telephone calls and included the following aspects: assistance to ease understanding of the patients' discharge letter; evaluation of the caregivers' support needs; caregivers' prioritization regarding urgent needs; and nurses' collaborative guidance in relation to access to such help. When compared to the controls, care preparedness was improved in the intervention group at moments 1 (4 days after discharge) and 2 (15-21 days after discharge), as well as from moment 1 to moment 3 (6 days after discharge). These improvements corresponded to a change of approximately 2 points in the Care Preparedness instrument(22-23).

Likewise, in Hong Kong, the effectiveness of a psychoeducational program targeted at care competence strength was evaluated, as well as the coping skills for problem-solving, the caregivers' depressive symptoms and the physical care burden and resources in stroke survivors, in 128 patient-caregivers dyads (64 in the control group and another 64 in the intervention group). The family caregivers from the intervention group were offered a psychoeducational program taught by a registered nurse with experience in psychiatric and general health conditions. The program consists of the following: (a) affective experience, which guides the caregivers towards a positive emotional response to everyday stress; (b) behavioral regulation, which modifies care skills and habits to promote the caregivers' health; and (c) the cognitive domain, which reformulates the perception about the problems and strengthens the problem-solving skills and expertise. Throughout the study, the intervention group showed significantly greater improvements in terms of care competence, coping skills for problem-solving and satisfaction with the social support received(24).

Nationwide, the findings are similar to those from another study, where the intention was to know the effect of an educational intervention for family caregivers of people with cancer in surgery and which presented significant changes in the knowledge category among the intervention group participants(16).

As pointed out in another study that was conducted in Pasto and which evaluated the impact of the pedagogical intervention on the care competence, it is verified that it is necessary to devise educational and comprehensive interventions that contribute to increasing the patient-caregiver dyad's knowledge level about the disease, so as to enhance their wisdom, favor behavioral changes and improve their care skills(18), as low knowledge levels have been observed in people with chronic diseases(19).

In turn, other categories that were improved among the caregivers from the intervention group were uniqueness and enjoying. Uniqueness refers to the tools and skills that people have to face problems(6), similarly to what was found in another two studies where the caregivers obtained high scores in this category(19,25). Enjoying indicates a person's well-being status and their perception about their quality of life(6); in other studies, low scores are usually obtained in this category due to two main aspects: they do not perceive any personal satisfaction when performing the caregiver role; and the fact that the many hours they devote to care prevent them from developing their life plan or materializing their personal projects, which makes the caregivers' burden visible(19,25).

Finally, the Anticipation category, which refers to the notions and ideas they have to anticipate the needs and problems that the patient-family caregiver dyad might face(6), was found to be favorable in two studies(19,25), which indicates that caregivers are on the alert about what the person cared for might require now and in the future. We might set forth whether this is true for caregivers about themselves, as it would be a fundamental aspect to consider in self-care, in order to prevent or reduce their burden.

On the other hand, no statistically significant differences were obtained regarding therapeutic adherence when comparing the control and intervention groups in the current research, which differs from a quasi-experimental study developed in Colombia with the intention of determining the effectiveness of a nursing intervention to improve therapeutic adherence in hypertensive patients. That study noticed improved adherence in the experimental group because of the adapted intervention called "*Desplegando mis recursos personales*" ("Deploying my personal resources"); in other words, the effectiveness of a psychosocial intervention to improve therapeutic adherence in the experimental group was shown, which obtained 86.6% against 11.4% in the control group(8). This shows that it is necessary to deploy different types of interventions that address a person's possible adherence to their treatment from different angles, as this not only implies following their pharmacological treatment but that the patients' knowledge should also be taken into account, as well as their needs, wishes and access to health services that may improve their quality of life.

On the other hand, the urgent need to seek proper transitional care from the clinical setting to the community environment for people with chronic conditions and their family caregivers is identified among the practical implications of this study; as this is both a higher-risk moment(17) and an excellent opportunity to reinforce the diverse knowledge, skills, behaviors and attitudes indispensable to increase the dyads' quality of life and well-being. It is precisely at this time that it becomes useful to determine the care competence in the patient-caregiver dyad to devise comprehensive programs and interventions, as nurses play an important role in their creation and implementation for being part of the support network for chronic patients and their caregivers(20).

As study strengths, we should note the fact that this is one of the few studies that have evaluated the impact of a Hospital Discharge Transition Program on the care competence in dyads comprised by patients with chronic conditions and their caregivers in a medium-low income country. Having used validated instruments such as the CUIDAR and the caregiver burden scales can also be mentioned; in addition, the baseline characteristics in the intervention and control groups did not present statistically significant differences; in other words, the groups were comparable due to randomization, with which it was sought to reduce the information and selection biases, respectively. Contamination of the sample was avoided, as the patients randomized to one group did not share information or interacted with the other; in addition, the educational intervention offered to the patient-caregiver dyads was conducted in a personalized way in the personal cubicles or rooms or at a private room from the health institutions. Double-masking was also applied: for the evaluator and for the person analyzing the data.

On the other hand, the study limitations were as follows: sample size and follow-up losses at month 1 among the dyads, due to two important factors: patients' deaths and the fact that some dyads live in distant areas from Santander, which hindered communication and complying with the phone follow-up due to the multiple tasks mainly in charge of the caregivers, and also for the difficulty accessing phone and data signals experienced by some of the participants in certain areas. However, the losses were similar in both groups (p-value=0.78) and an intention-to-treat analysis was performed, assuming that the dyads lost did not present changes in the variables during follow-up.

In addition, at the baseline assessment there were statistically significant differences in the perceived burden level among the family caregivers from the control and intervention groups and intense burden was higher in the intervention group, which may have influenced the fact that no differences were found between both groups. It was also not possible to mask the study participants due to the nature of the intervention.

Although the study participants mostly use cell phones and instant messaging apps such as WhatsApp, this does not ensure that the educational intervention offered via telephone meets its objective, due to other possible factor that may exert an influence on knowledge acquisition and transfer.

Another aspect that may have influenced the absence of differences between the groups is that the control group was offered basic education on adherence and transitional care at the institutions with the aid of a booklet, which might have been similar to the main intervention of the transition plan and underestimate the effect, as significant Delta values were observed after the intervention in both groups among patients and caregivers alike.

Conclusion

The Hospital Discharge Transition Program allowed increasing the care competence both in the patients and in the caregivers, as well as the patients' adherence to the therapeutic treatment, as significant post-intervention values were obtained when compared to those before the intervention; however, when comparing these effects with those obtained in the control group, no differences were evidenced between the groups. This finding is probably due to the fact that the control group was offered the usual transition plan by the institution and to having resorted to the aid of a basic educational booklet provided by the research team, complying with a request from the Ethics Committee, which may have rendered it similar to the main intervention of the transition plan and underestimated or diluted its effect.

Therefore, the activities that are conducted under the Hospital Discharge Transition Plan for patients with cardiovascular chronic conditions and their family caregivers targeted at improving adherence, lifestyles and compliance with indications performed at the health institution allow increasing the care competence scores of both patients and caregivers, as they constitute a tool to educate, support and guide home-based care in order to avoid or reduce complications and improve well-being in patients and family caregivers alike. Likewise, it is useful for health institutions to have a standardized strategy to provide care and ease the hospital discharge process with the aid of educational material and recommendations targeted at controlling diseases and preserving health, which may increase care quality. The suggestions for future research studies are to complement the transition plan with activities targeted at improving therapeutic adherence and offering other alternatives in addition to phone follow-up, such as nursing consultations or home visits, support from information technologies, increasing the sample size, clearly differentiating the activities in the intervention and control groups and, finally, longer follow-up periods to determine sustainability of the intervention effect over time.

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